

and shaped to extend through the inner tube lumen, and wherein the strand is releasably coupled to a portion of the clip.

43. (New) The system of claim 42, further including a ring, the ring sized and shaped to be carried within the outer tube lumen, and sized and shaped to engage a distal end of the inner tube, and sized and shaped to encircle a portion of the clip to close and hold the clip around the portion of the aneurysm.

44. (New) The system of claim 37, further including an entry device, the entry device including:

a first securing mechanism to secure the entry device in association with the subject's skull; and

a second securing mechanism to secure an orientation of a trajectory guide portion of the entry device to define a path between the minimally-invasive opening and the aneurysm.

45. (New) The system of claim 44, further including means for providing information upon which the orientation of the trajectory guide is determined.

46. (New) The system of claim 45, further including a local imaging device located near the distal end of the probe.

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on November 19, 2002, and the references cited therewith.

Claims 1 and 32 are amended. No claims are canceled. Claims 37-46 are added. As a result, claims 1-5, 7-14, 16-17, 24-25, 32-46 are now pending in this application.

§102 Rejection of the Claims

Claims 1 and 7-14 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schmidt (U.S. Patent No. 5,634,932). Applicant traverses. Applicant can find no disclosure in Schmidt of a probe that includes a substantially uniform cylindrical outer surface that is sized and shaped to be accepted within and guided by a similarly sized and shaped lumen of a trajectory guide device, as presently recited or incorporated in these claims. (See, e.g., Application at Figs. 3-5.) Indeed, Figs. 9-12 of Schmidt apparently illustrate an irregularly-shaped distal end that includes perpendicular projections therefrom for carrying the aneurysm clip. (See Schmidt at column 8 lines 48-61.) Therefore, the apparatus of Schmidt is ill-suited for being guided within a guide lumen of a trajectory guide device. A trajectory guide device is useful, for example, in image-guided neurosurgery for clipping an aneurysm. In such an image-guided neurosurgery procedure, preoperative magnetic resonance (MR) or other images are used to steer an instrument toward a target using the trajectory guide. The orientation of the trajectory guide can be established using the preoperative images. Visual observation of the target is not required. By contrast, Schmidt is expressly directed toward surgical procedures requiring visual observation of the target aneurysm. (See, e.g., Schmidt at column 4, lines 4-17.)

Regarding claim 7, Applicant can find no disclosure in Schmidt of at least one of the aneurysm treatment device and the distal end of the probe including at least one of an MR or CT imagable fiducial structure, as recited in claim 7.

Regarding claim 13, Applicant can find no disclosure in Schmidt of an aneurysm treatment device that is shaped to be extendable from and retractable into a lumen of the probe, as recited in claim 13. In fact, Schmidt actually teaches away from such extension and retraction. (See Schmidt at column 4, lines 4-6).

In sum, because Schmidt does not disclose all elements presently recited or incorporated in claims 7-14, Applicant respectfully requests withdrawal of this basis of rejection.

§103 Rejection of the Claims

1. Claims 16 and 17 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmidt. Applicant traverses. The Examiner's burden of establishing a *prima facie* case of

obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142. However, this single-reference obviousness rejection expressly acknowledges that the elongate member of Schmidt et al. is not disclosed as a tube. (*See* Office Action at 3.) Instead, the rejection states:

Applicant has set forth no criticality as to why a "tube" shape of the elongate member is necessary, for any particular purpose, or solves any stated problem and it appears that the invention would work equally well in the embodiment disclosed by Schmidt. Accordingly the use of the tube shape for the elongate member appears to be an obvious matter of engineering design.

(Office Action at 3.) Applicant disagrees. Without admitting to the criticality or necessity of a "tube" shape of the "elongate tube" recited or incorporated in these claims, Applicant submits that examples of suitable purposes of such a "tube" shape are set forth at several instances in the present patent application.

First, claim 16 itself speaks of an elongate tube that is "shaped to extend through the lumen of the probe." In one example, as illustrated in Figure 4 of the present patent application, this permits the elongate tube 406 to be guided within the lumen of probe 106, which, in turn, is sized and shaped to be guided within a lumen of a trajectory guide device, as illustrated in Fig. 3 of the present patent application.

Second, claim 16 itself also speaks of the elongate tube being shaped to extend out of the distal end of the probe and around a portion of the clip "to substantially close a portion of the clip around a portion of the aneurysm." In one example, as illustrated in Figure 5(c) of the present patent application, this permits the elongate tube to push the ring 402 around the clip 400 to close the clip 400 around an aneurysm. Thus, Applicant respectfully submits that the present claims do set forth a purpose of the tube that is not disclosed, taught, or suggested by Schmidt. ✓

Moreover, Applicant can find no disclosure, teaching, or suggestion in Schmidt of an exovascular aneurysm treatment probe that includes a substantially uniform cylindrical outer surface that is sized and shaped to be accepted within and guided by a similarly sized and shaped lumen of a trajectory guide device, as presently recited or incorporated in these claims. (*See, e.g.,* ✓

Application at Figs. 3-5.) Therefore, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims.

Indeed, Figs. 9-12 of Schmidt apparently illustrate an irregularly-shaped distal end that includes perpendicular projections therefrom for carrying the aneurysm clip. (See Schmidt at column 8 lines 48-61.) Therefore, the apparatus of Schmidt is ill-suited for being guided within a guide lumen of a trajectory guide device. Because Schmidt fails to disclose all presently claimed elements, and because Schmidt actually teaches away from using trajectory guidance and image-guided neurosurgery, Applicant respectfully submits that claims 16-17 are patentable, and respectfully requests withdrawal of this basis of rejection of these claims. ✓

2. Claims 24 and 25 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmidt in view of Sheldon et al. (U.S. Patent No. 4,386,602). Applicant traverses. The Examiner's burden of establishing a *prima facie* case of obviousness requires, among other things, that each and every one of the recited claim limitations are taught or suggested in the cited prior art reference(s) independent of the teaching in the applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142. However, Applicant can find no disclosure, teaching, or suggestion in Schmidt or Sheldon of an exovascular aneurysm treatment probe that includes a substantially uniform cylindrical outer surface that is sized and shaped to be accepted within and guided by a similarly sized and shaped lumen of a trajectory guide device, as presently recited or incorporated in these claims. (See, e.g., Application at Figs. 3-5.) Therefore, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims. ✓

Indeed, Figs. 9-12 of Schmidt apparently illustrate an irregularly-shaped distal end that includes perpendicular projections therefrom for carrying the aneurysm clip. (See Schmidt at column 8 lines 48-61.) Therefore, the apparatus of Schmidt is ill-suited for being guided within a guide lumen of a trajectory guide device. A trajectory guide device is useful, for example, in image-guided neurosurgery for clipping an aneurysm. In such an image-guided neurosurgery procedure, preoperative magnetic resonance (MR) or other images are used to steer an instrument toward a target using the trajectory guide. The orientation of the trajectory guide can be established using the preoperative images. In image-guided neurosurgery using a trajectory guide

device, visual observation of the target is not required. By contrast, Schmidt is expressly directed toward surgical procedures requiring visual observation of the target aneurysm. (*See, e.g.*, Schmidt at column 4, lines 4-17.) Therefore, Schmidt actually teaches away from being combined with Sheldon et al. Because Schmidt and Sheldon et al. fail to disclose all presently claimed elements, and because Schmidt actually teaches away from using trajectory guidance and image-guided neurosurgery, Applicant respectfully submits that claims 24-25 are patentable, and respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 2-5 and 32-35 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Schmidt in view of Gillies et al. (U.S. Patent No. 6,272,370). Applicant traverses. Applicant respectfully submits that no prima facie case of obviousness presently exists with respect to these claims, on the same grounds as discussed above with respect to claims 24-25 in view of Schmidt and Sheldon et al. Applicant further reiterates that because Schmidt et al. is expressly directed toward the problem of providing improved visual observation of placing the aneurysm clip, Schmidt et al. actually teaches away from including structures for providing or enhancing imaging during the surgical placement of the aneurysm clip. (*See, e.g.*, Schmidt at column 4, lines 4-17.) Therefore, Schmidt actually teaches away from being combined with Gillies et al. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims. ✓
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4. Claim 36 was rejected under 35 USC § 103(a) as allegedly obvious over Schmidt in view of Gillies et al. and further in view of Sheldon et al. Applicant traverses. Applicant respectfully submits that no prima facie case of obviousness presently exists with respect to these claims, on the same grounds as discussed above with respect to claims 24-25 in view of Schmidt and Sheldon et al., and as discussed above with respect to claims 2-5 and 32-35 in view of Schmidt and Gilles et al. Applicant further reiterates that because Schmidt et al. is expressly directed toward the problem of providing improved visual observation of placing the aneurysm clip, Schmidt et al. actually teaches away from including structures for providing or enhancing imaging during the surgical placement of the aneurysm clip. (*See, e.g.*, Schmidt at column 4, lines 4-17.) Therefore, Schmidt actually teaches away from being combined with Gillies et al. and/or Sheldon et al. Accordingly, Applicant respectfully requests withdrawal of this basis of

rejection of these claims.

New Claims

Applicant has added new claims 37-46 to more particularly point out and distinctly claim subject matter. Applicant respectfully submits that these new claims are fully supported by the originally-filed patent application, and are allowable over the art of record. Accordingly, Applicant respectfully requests allowance of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6951) to facilitate prosecution of this application.

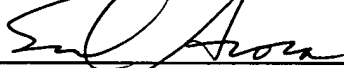
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Respectfully submitted,

RUDY A. MAZZOCCHI ET AL.

By their Representatives,

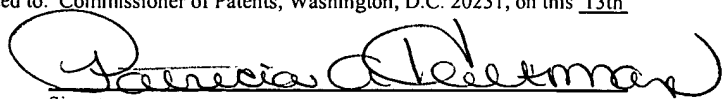
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6951

Date Feb. 13, 2003 By 

Suneel Arora
Reg. No. 42,267

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 13th day of February, 2003.

PATRICIA A. HULTMAN
Name


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